K003434

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

General Information

A. Submitted By:

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Contact: David Kolesar
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B. Device Trade Name: ALLEGRO Imaging System
Models: ALLEGRO TB (body scanner)
ALLEGRO N (small patient and brain scanner)
Common Name: Positron Emission Tomograph
Classification Name: System, Emission Computed Tomography, (892.1200)
Device Class: 21CFR 892.1200, Class II
Product Code: 90 KPS

C. Date prepared: October 16, 2000

D. Predicate Device: C-PET Imaging System (K9773396)

E. Intended Use:

The ALLEGRO Imaging System is intended to produce images depicting the anatomical distribution of single photon and positron emitting radioisotopes within the human body for interpretation by medical personnel.

F. Device Description:

The ALLEGRO Positron Emission Tomography (PET) system is available either as a dedicated brain scanner (N model) or as a whole body scanner (TB model). Both versions are designed to provide true volumetric imaging. ALLEGRO is intended for diagnostic imaging. When used with appropriate radiopharmaceuticals, it produces images representative of the internal distribution of radioactivity in the head or the body.

The system allows you to reconstruct high-resolution three-dimensional, static, gated or dynamic images of biochemical and metabolic processes and then enables you to display, process and analyze these images according to your specific needs.

PET is based on the fact that certain radionuclides decay by positron emission. The subsequent positron annihilation results in the creation of two 511 keV gamma rays which are emitted in opposite directions. Coincidence detection of both gamma rays localizes the decay along a line. By using a full ring of many detectors around the patient, counts along many parallel lines and at many angles are acquired simultaneously. By using reconstruction algorithms, the internal distribution of radioactivity can be determined.

The brain scanner provides a 25 cm transverse field of view for imaging the brain or other small patients (e.g. infants) with very high spatial resolution; the whole-body scanner provides a 56 cm transverse field-of-view for both brain as well as body studies.

ALLEGRO uses a large number of small (4*4*10mm for N, 4*6*20mm for TB) scintillation crystals, coupled to either 288 photo-multipliers (PMTs) for the brain scanner, or 432 PMTs for the body scanner.

G. Comparison to Predicate Device:

ALLEGRO is basically the same as the predicate device C-PET with respect to overall system architecture, including major detector electronics, acquisition software, processing software, electrical power system and gantry. The key difference is the GSO detector material for ALLEGRO compared to NaI in C-PET. Modifications were made to the detector software and front electronics to accommodate the GSO material. The GSO crystal material offers several advantages over NaI used with C-PET in a number of clinically important areas including:

- Better spatial resolution in order to detect smaller lesions, achieved by improving the detector resolution from 5.5 mm to 4.8 mm.
- Better sensitivity in order to shorten the imaging time achieved by using a material with higher stopping power.
- Higher count rate capability in order to measure more events in a shorter time, achieved by using a material with faster scintillation decay time.

All of the above changes improve the existing PET scanner without altering its function.

H. System Performance Test:

ALLEGRO system performance was measured according to the NEMA-NU2 standard. In addition, clinical phantoms with clinical protocols were used to evaluate ALLEGRO image quality in terms of the noise texture and contrast of the image.

I. Conclusion:

The ALLEGRO Imaging System is substantially equivalent to the predicate device C-PET Imaging System based upon similar intended use, technological comparison, and system performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 6 2000

ADAC, Laboratories
c/o David Kolesar
TUV Rheinland of North America
12 Commerce Road
Newton, CT 06470

Re: K003434
ALLEGRO Imaging System
Dated: November 2, 2000
Received: November 6, 2000
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Kolesar:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE STATEMENT

510 (k) NUMBER (IF KNOWN): K003434

DEVICE NAME: ALLEGRO Imaging System

SPONSOR NAME: ADAC Laboratories

INDICATIONS FOR USE:

The ALLEGRO Imaging System is intended to produce images depicting the anatomical distribution of single photon and positron emitting radioisotopes within the body for interpretation by medical personnel.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David C. Ingram

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003434